Flame Retardant Alternatives

Proprietary H: Halogenated aryl ester

Hazard Review

Proprietary H: Halogenated aryl ester
Existing Data Summary Table – Human Health Endpoints

✓= Endpoint characterized by existing data * = Data available but not adequate ✘ = Endpoint not applicable

As noted in this key, a check mark indicates that an endpoint was adequately characterized by existing studies. It does not indicate a positive or negative result for that particular endpoint.

Acute Toxicity	
Oral	✓
Dermal	
Inhalation	
Eye irritation	
Dermal irritation	
Skin sensitization	
Subchronic Toxicity	
28-Day oral	
90-Day oral	
Combined repeated dose with reproduction/ developmental toxicity screen	
21/28-Day dermal	
90-Day dermal	
90-Day inhalation	
Reproductive Toxicity	
Reproduction/ developmental toxicity screen	
Combined repeated dose with reproduction/ developmental toxicity screen	
Reproduction and fertility effects	

Developmental Toxicity	
Reproduction/ developmental toxicity screen	
Combined repeated dose with reproduction/ developmental toxicity screen	
Prenatal developmental	
Chronic Toxicity	
Chronic toxicity (two species)	
Combined chronic toxicity/ carcinogenicity	
Carcinogenicity	
Carcinogenicity (rat and mouse)	
Combined chronic toxicity/ carcinogenicity	

Neurotoxicity	
Acute and 28-day delayed neurotoxicity of organophosphorus substances (hen)	
Neurotoxicity screening battery (adult)	
Developmental neurotoxicity	
Additional neurotoxicity studies	
Immunotoxicity	
Immunotoxicity	
Genotoxicity	
Gene mutation in vitro	
Gene mutation in vivo	
Chromosomal aberrations in vitro	
Chromosomal aberrations in vivo	
DNA damage and repair	
Other	

Proprietary H: Halogenated aryl ester
Existing Data Summary Table – Properties, Fate, and Ecotoxicity

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As noted in this key, a check mark indicates that an endpoint was adequately characterized by existing studies. It does not indicate a positive or negative result for that particular endpoint.

P/Chem Properties	
Water solubility	
Octanol/water partition coefficient	
Oxidation/reduction	
Melting point	
Boiling point	
Vapor pressure	
Odor	
Oxidation/reduction chemical incompatibility	
Flammability	
Explosivity	
Corrosion characteristics	
pH	
UV/visible absorption	
Viscosity	
Density/relative density/bulk density	
Dissociation constant in water	
Henry's Law constant	

Environmental Fate	
Bioconcentration	
Fish	✓
Daphnids	
Green algae	
Oysters	
Earthworms	
Metabolism in fish	
Degradation and Transport	
Photolysis, atmosphere	
Photolysis, water	
Photolysis in soil	
Aerobic biodegradation	✓
Anaerobic biodegradation	
Porous pot test	
Pyrolysis	
Hydrolysis as a function of pH	✓
Sediment/water biodegradation	✓
Soil biodegradation w/ product identification	
Indirect photolysis in water	
Sediment/soil adsorption/desorption	✓

Ecotoxicity	
Aquatic Toxicity	
Fish acute LC50	✓
Daphnia acute EC50	✓
Mysid shrimp acute LC50	
Green algae EC50, NOAEC, LOAEC	✓
Fish chronic NOAEC, LOAEC	
Daphnia chronic NOAEC, LOAEC	
Mysid shrimp chronic NOAEC, LOAEC	
Terrestrial Organism Toxicity	
Bird LD50 (two species)	
Bird LC50 (two species)	
Bird reproduction	
Earthworm subchronic EC50, LC50, NOAEC, LOAEC	

Chemical Identity

Proprietary H: Halogenated aryl ester
CAS
MF
MW
SMILES

Human Health Endpoints

ACUTE TOXICITY

Acute Oral Toxicity (OPPTS Harmonized Guideline 870.1100; OECD Guidelines 425, 420, 423, 401)

Conclusion:

The available acute oral toxicity data were judged adequate to meet the endpoint.

Basis for Conclusion:

The available acute oral lethality study was conducted according to EEC acute toxicity methods for fixed-dose studies. Methodological procedures appear consistent with OECD methods for acute oral toxicity testing (i.e., OECD Guideline 401). The study appears adequate.

Type: Acute oral LD50
Species, strain, sex, number: Rat, Sprague-Dawley, 5 males and 5 females
Dose: 2000 mg/kg
Purity: 99.7%
Vehicle: Not indicated
Observation period: 14 days post dosing
Method: Directive 92/69/EEC (OJ No. L383A, 29.12.92), Part B, Method B.1 bis. Acute toxicity (oral), fixed-dose method.
Results: No deaths; therefore, LD50 >2000 mg/kg. Piloerection and hunched posture in 10/10 rats; recovery by post-exposure day 4.
Reference: Ref. 1

No studies were submitted that conformed to the following guidelines.

- **Acute Dermal Toxicity (OPPTS Harmonized Guideline 870.1200; OECD Guideline 402)**
- **Acute Inhalation Toxicity (OPPTS Harmonized Guideline 870.1300 (OECD Guideline 403)**
- **Acute Eye Irritation (OPPTS Harmonized Guideline 870.2400; OECD Guideline 405)**

- **Acute Dermal Irritation (OPPTS Harmonized Guideline 870.2500; OECD Guideline 404)**

Skin Sensitization (OPPTS Harmonized Guideline 870.2600; OECD Guideline 429)

***Conclusion*:**

The skin sensitization endpoint is not satisfied.

Basis for Conclusion

No studies were located that followed or were similar to the guideline listed above or otherwise addressed skin sensitization.

SUBCHRONIC TOXICITY

Conclusion:

No available subchronic toxicity data.

Basis for Conclusion:

No pertinent studies were located that addressed the subchronic toxicity endpoints in the guidelines listed below.

Subchronic Oral Toxicity (28-day, 90-day, or combined with reproductive/developmental)
- **Repeated Dose 28-Day Oral Toxicity in Rodents (OPPTS Harmonized Guideline 870.3050; OECD Guideline 407)**
- **90-Day Oral Toxicity in Rodents (OPPTS Harmonized Guideline 870.3100; OECD Guideline 408)**,
- **Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OPPTS Harmonized Guideline 870.3650; OECD Guideline 422), respectively**.

Subchronic Dermal Toxicity (21/28-day or 90-day).
- **21/28-Day Dermal Toxicity (OPPTS Harmonized Guideline 870.3200 (OECD Guideline 410)**
- **90-Day Dermal Toxicity (OPPTS Harmonized Guideline 870.3250; OECD Guideline 411)**

Subchronic Inhalation Toxicity (90 day)
- **90-Day Inhalation Toxicity (OPPTS Harmonized Guideline 870.3465; OECD Guideline 413)**

REPRODUCTIVE TOXICITY

Conclusion:

No available reproductive toxicity data.

Basis for Conclusion:

No pertinent studies were located that addressed the reproductive toxicity endpoints in the guidelines listed below.

- **Reproduction/Developmental Toxicity Screening (OPPTS Harmonized Guideline 870.3550; OECD Guideline 421)**
- **Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OPPTS Harmonized Guideline 870.3650; OECD Guideline 422)**
- **Reproduction and Fertility Effects (OPPTS Harmonized Guideline 870.3800; OECD Guideline 416)**

DEVELOPMENTAL TOXICITY

Conclusion:

No available developmental toxicity data.

Basis for Conclusion:

No pertinent studies were located that addressed the developmental toxicity endpoints in the guidelines listed below.

- **Prenatal Developmental Toxicity Study (OPPTS Harmonized Guideline 870.3700; OECD Guideline 414)**
- **Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OPPTS Harmonized Guideline 870.3650; OECD Guideline 422)**
- **Reproduction/Developmental Toxicity Screening (OPPTS Harmonized Guideline 870.3550; OECD Guideline 421)**

CHRONIC TOXICITY

Conclusion:

No available chronic toxicity data.

Basis for Conclusion:

No pertinent studies were located that addressed the chronic toxicity endpoints in the guidelines listed below.

- **Chronic Toxicity (OPPTS Harmonized Guideline 870.4100; OECD Guideline 452)**
- **Combined Chronic Toxicity/Carcinogenicity (OPPTS Harmonized Guideline 870.4300; OECD Guideline 453)**

CARCINOGENICITY

Conclusion:

No available carcinogenicity data.

Basis for Conclusion:

No pertinent studies were located that addressed the carcinogenicity endpoints in the guidelines listed below.

- **Carcinogenicity (OPPTS Harmonized Guideline 870.4200; OECD Guideline 451)**
- **Combined Chronic Toxicity/Carcinogenicity (OPPTS Harmonized Guideline 870.4300; OECD Guideline 453)**

NEUROTOXICITY

Conclusion:

No available neurotoxicity data.

Basis for Conclusion:

No neurotoxicity studies were located that addressed the endpoints in the guidelines listed below.

Delayed Neurotoxicity
- **Acute and 28-Day Delayed Neurotoxicity of Organophosphorus Substances (OPPTS Harmonized Guideline 870.6100; OECD Guideline 418, 419)**

Neurotoxicity (Adult)
- **Neurotoxicity Screening Battery (OPPTS Harmonized Guideline 870.6200; OECD Guideline 424)**

Developmental Neurotoxicity
- **Developmental Neurotoxicity: Developmental Neurotoxicity Study (OPPTS Harmonized Guideline 870.6300)**

IMMUNOTOXICITY

Conclusion:

No available immunotoxicity data.

Basis for Conclusion:

No immunotoxicity studies were located that addressed the endpoints in the guidelines listed below.

- **Immunotoxicity (OPPTS Harmonized Guideline 870.7800)**

GENOTOXICITY

Conclusion:

No available genotoxicity data.

Basis for Conclusion:

No genotoxicity studies relevant to the below categories or to other types of genotoxic effects were located.

Gene Mutation in Vitro
Gene Mutation in Vivo
Chromosomal Aberrations in Vitro
Chromosomal Aberrations in Vivo
DNA Damage and Repair

Ecotoxicity

Acute Toxicity to Aquatic Organisms

Conclusion:

- The available acute freshwater toxicity data for fish, aquatic invertebrates, and algae were judged adequate to meet the endpoints.
- The available acute marine/estuary toxicity data for fish, aquatic invertebrates, and algae were judged inadequate to meet the endpoints.

Basis for Conclusion:

Acute Toxicity to Freshwater and Marine Fish (OPPTS Harmonized Guideline 850.1075; OECD Guideline 203)

A confidential 96-hour study in fish was located that reported no effects at saturation. These data allow this endpoint to be adequately characterized.

Acute Toxicity to Freshwater Invertebrates (OPPTS Harmonized Guideline 850.1010; OECD Guideline 202)

A confidential study in daphnid was located that reported a 24-hour EC50 of 1.2 mg/L and a 48-hour EC50 of 0.42 mg/L. These data allow this endpoint to be adequately characterized.

Algal Toxicity (OPPTS Harmonized Guideline 850.5400; OECD Guideline 201)

A confidential 96-hour study in green algae was located that reported no effects at saturation. These data allow this endpoint to be adequately characterized.

No additional acute toxicity studies with freshwater or saltwater fish, aquatic invertebrates, or algae were located that followed or were similar to the guideline protocols listed below.

- **Acute Toxicity to Freshwater and Marine Fish (OPPTS Harmonized Guideline 850.1075; OECD Guideline 203)**
- **Acute Toxicity to Marine/Estuarine Invertebrates (OPPTS Harmonized Guideline 850.1035)**
- **Algal Toxicity (OPPTS Harmonized Guideline 850.5400; OECD Guideline 201)**

Chronic Toxicity to Aquatic Organisms

Conclusion:

No available chronic toxicity data for fish and aquatic invertebrates.

Basis for Conclusion:

No pertinent chronic toxicity studies with fish or aquatic invertebrates were located that addressed the endpoints in the guidelines listed below.

- **Chronic Toxicity to Freshwater and Marine Fish (OPPTS Harmonized Guideline 850.1400; OECD Guideline 210)**
- **Chronic Toxicity to Freshwater Invertebrates (OPPTS Harmonized Guideline 850.1300; OECD Guideline 211)**
- **Chronic Toxicity to Marine/Estuarine Invertebrates (OPPTS Harmonized Guideline 850.1350)**

<u>Acute and Subchronic Toxicity to Terrestrial Organisms</u>

Conclusion:

No available acute and subchronic toxicity data for terrestrial organisms.

Basis for Conclusion:

No pertinent acute oral, acute dietary, or reproductive toxicity studies with birds and no subchronic toxicity studies with earthworms were located that addressed the endpoints in the guidelines listed below.

- **Acute Oral Toxicity in Birds (OPPTS Harmonized Guideline 850.2100)**
- **Acute Dietary Toxicity in Birds (OPPTS Harmonized Guideline 850.2200; OECD Guideline 205)**
- **Reproductive Toxicity in Birds (OPPTS Harmonized Guideline 850.2300; OECD Guideline 206)**
- **Earthworm Subchronic Toxicity (OPPTS Harmonized Guideline 850.6200; OECD Guideline 207)**

Physical/Chemical Properties

Proprietary H: Halogenated aryl ester
CAS
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MW
SMILES

Water Solubility (mg/L): No data

Log K_{ow}: No data

Oxidation/Reduction: No data

Melting Point: No data

Vapor Pressure (torr): No data

Odor: No data

Oxidation/Reduction Chemical Incompatibility: No data

Flammability:

Conclusion: The flammability (as the flash point) has been adequately characterized.

Basis for Conclusion: The key study was performed according to EEC Methods, Directive 92/69/EEC (OJ No. L383A, 29.12.92), Part A, Method A9, flash point.

Flash Point: 215°C (Ref. 2)

Explosivity: No data

Corrosion Characteristics: No data

pH: No data

UV/VIS Absorption: No data

Viscosity: No data

Density/Relative Density/Bulk Density: No data

Dissociation Constant in Water: No data

Henry's Law Constant: No data

Environmental Fate

Bioconcentration

Fish:

Conclusion:

The available bioconcentration data are adequate.

Basis for Conclusion:

A confidential guideline study submitted on Proprietary H indicates that the bioconcentration factor is 1.7-6.2.

Daphnids: No data

Green Algae: No data

Oysters: No data

Earthworms: No data

Fish Metabolism: No data

Degradation

Photolysis in the Atmosphere: No data

Photolysis in Water: No data

Photolysis in Soil: No data

Aerobic Biodegradation:

Conclusion:

The available aerobic biodegradation data are adequate.

Basis for Conclusion:

A confidential study submitted on Proprietary H indicates that its half life is 3.5 days in water in a shake flask die-away test. It was also found to undergo 6% biodegradation after 28 days in closed bottle test in a submitted confidential study.

Anaerobic Biodegradation: No data

Porous Pot Test: No data

Pyrolysis: No data

Hydrolysis as a Function of pH:

Conclusion:

The available hydrolysis as a function of pH data are adequate.

Basis for Conclusion:

A confidential study submitted on Proprietary H indicates that its hydrolysis half life is >1 year at pH 4, 7, and 9.

Sediment/Water Biodegradation:

Conclusion:

The available sediment/water biodegradation data are adequate.

Basis for Conclusion:

A confidential study submitted on Proprietary H indicates that its half life is 8.5 days in sediment in a shake flask die-away test.

Soil Biodegradation with Product Identification: No data

Indirect Photolysis in Water: No data

Sediment/Soil Adsorption/Desorption:

Conclusion:

The available soil adsorption data are adequate.

Basis for Conclusion:

A confidential study submitted on Proprietary H indicates that the soil adsorption coefficient is >28,840.